

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

FIKES *et al.*

Appl. No. 09/458,299

Filed: December 10, 1999

For: **Inducing Cellular Immune
Responses to HER2/neu Using
Peptide and Nucleic Acid
Compositions**

Confirmation No. 8698

Art Unit: 1644

Examiner: Schwadron, R.B.

Atty. Docket: 2060.0140000/EKS/HCC/M-

First Supplemental Information Disclosure Statement

Commissioner for Patents
Washington, D.C. 20231

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98. The numbering on this First Supplemental Information Disclosure Statement is a continuation of the numbering in Applicants' Information Disclosure Statement filed herewith in connection with the above-captioned application. A copy of each document is also provided.

The Examiner is referred to the following list of related, co-pending patent applications:

U.S. Patent Application No. 08/205,713, filed March 4, 1994, inventor Grey, submitted herewith as Document AT28;

U.S. Patent Application No. 08/344,824, filed November 23, 1994, inventors Sette *et al.*, submitted herewith as Document AR29;

U.S. Patent Application No. 08/347,610, filed December 1, 1994, inventors Kubo *et al.*, submitted herewith as Document AS29;

U.S. Patent Application No. 09/017,524, filed February 3, 1998, inventors Kubo *et al.*, submitted herewith as Document AT29;

U.S. Patent Application No. 10/149,138, filed December 11, 2002, inventors Fikes *et al.*, submitted herewith as Document AR30.

The identification of the listed U.S. Patent Applications is not to be construed as a waiver of secrecy as to these applications now or upon issuance of the present application as a patent. The Examiner is respectfully requested to consider the cited applications and the art cited therein during examination.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered. This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist.

This Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits. No statement or fee is required.

Consideration of the cited documents and making the same of record in the prosecution of the above-identified application is respectfully requested. The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Helene C. Carlson
Agent for Applicants
Registration No. 47,473

Date: 3/21/03

1100 New York Avenue, N.W.
Suite 600
Washington, D.C. 20005-3934
(202) 371-2600

FORM PTO-1449 FIRST SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT	ATTY. DOCKET NO. 2060.0140000/EKS/HCC/M-M	APPLICATION NO. 09/458,299
	APPLICANT FIKES et al.	
	FILING DATE December 10, 1999	GROUP 1644

U.S. PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA						
	AB						
	AC						
	AD						
	AE						
	AF						
	AG						
	AH						
	AI						
	AJ						
	AK						

FOREIGN PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	27	Kawashima, I., et al., "The Multi-epitope Approach for Immunotherapy for Cancer: Identification of Several CTL Epitopes from Various Tumor-Associated Antigens Expressed on Solid Epithelial Tumors," <i>Hum. Immunol.</i> 59:1-14, Elsevier Science, Inc. (January 1998)
	AS	27	Kawashima, I., et al., "Identification of HLA-A3-restricted Cytotoxic T Lymphocyte Epitopes from Carcinoembryonic Antigen and HER-2/neu by Primary in Vitro Immunization with Peptide-pulsed Dendritic Cells," <i>Cancer Res.</i> 59:431-435, American Association for Cancer Research (January 1999)
	AT	27	Knuth, A., et al., "Cellular and humoral immune responses against cancer: implications for cancer vaccines," <i>Curr. Opin. Immunol.</i> 3:659-664, Current Biology, Ltd. (1991)

EXAMINER	DATE CONSIDERED
----------	-----------------

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

FORM PTO-1449 FIRST SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT	ATTY. DOCKET NO. 2060.0140000/EKS/HCC/M-M	APPLICATION NO. 09/458,299
	APPLICANT FIKES et al.	
	FILING DATE December 10, 1999	GROUP 1644

U.S. PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE
	AA						
	AB						
	AC						
	AD						
	AE						
	AF						
	AG						
	AH						
	AI						
	AJ						
	AK						

FOREIGN PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION
	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			
AR	<u>28</u>	Lustgarten, J., et al., "Identification of Her-2/Neu CTL Epitopes Using Double Transgenic Mice Expressing HLA-A2.1 and Human CD.8," <i>Hum. Immunol.</i> 52:109-118, Elsevier Science, Inc. (February 1997)	
AS	<u>28</u>	Toes, R.E.M., et al., "Enhancement of Tumor Outgrowth Through CTL Tolerization After Peptide Vaccination Is Avoided by Peptide Presentation on Dendritic Cells," <i>J. Immunol.</i> 160:4449-4456, The American Association of Immunologists (May 1998)	
AT	<u>28</u>	Copy of co-pending U.S. application 08/205,713, inventor Grey, filed March 4, 1994 (NOT PUBLISHED).	

EXAMINER	DATE CONSIDERED
EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.	

FORM PTO-1449 FIRST SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT	ATTY. DOCKET NO. 2060.0140000/EKS/HCC/M-M	APPLICATION NO. 09/458,299
	APPLICANT FIKES et al.	
	FILING DATE December 10, 1999	GROUP 1644

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE
	AA						
	AB						
	AC						
	AD						
	AE1	5,783,567	07/21/1998	Hedley et al.			01/22/1997
	AF1	5,876,712	03/02/1999	Cheever et al.			06/06/1995
	AG1	6,037,135	03/14/2000	Kubo et al.			11/29/1993
	AH1	6,075,122	06/13/2000	Cheever et al.			06/06/1995
	AI1	2002/0168374 A1	11/14/2002	Kubo et al.			03/20/1997
	AJ1	2002/0177694 A1	11/28/2002	Sette et al.			02/03/1998
	AK1	2002/0098197 A1	07/25/2002	Sette et al.			05/30/1995

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION
	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR		
	AS	26	Boon, T., "Tumor antigens recognized by cytolytic T lymphocytes: present perspectives for specific immunotherapy," <i>Int. J. Cancer</i> 54:177-180, Wiley-Liss, Inc. (May 1993)
	AT	26	Cotran, R.S., et al., "Neoplasia," in <i>Robbins Pathologic Basis of Disease</i> , 4 th ed., W.B. Saunders Staff, ed., W.B. Saunders Company, Philadelphia, PA, pp. 296-299 (1989)

EXAMINER	DATE CONSIDERED
EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.	

FORM PTO-1449
**FIRST SUPPLEMENTAL
 INFORMATION DISCLOSURE STATEMENT**

ATTY. DOCKET NO.
 2060.0140000/EKS/HCC/M-M

APPLICATION NO.
 09/458,299

APPLICANT
 FIKES *et al.*

FILING DATE
 December 10, 1999

GROUP
 1644

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE
	AA						
	AB						
	AC						
	AD						
	AE						
	AF						
	AG						
	AH						
	AI						
	AJ						
	AK						

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION
	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>29</u>	Copy of co-pending U.S. application 08/344,824, inventors Sette <i>et al.</i> , filed November 23, 1994 (NOT PUBLISHED).
	AS	<u>29</u>	Copy of co-pending U.S. application 08/347,610, inventors Kubo <i>et al.</i> , filed December 1, 1994 (NOT PUBLISHED).
	AT	<u>29</u>	Copy of co-pending U.S. application 09/017,524, inventors Kubo <i>et al.</i> , filed February 3, 1998 (NOT PUBLISHED).

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

FORM PTO-1449

FIRST SUPPLEMENTAL
INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO.
2060.0140000/EKS/HCC/M-M

APPLICATION NO.
09/458,299

APPLICANT
FIKES et al.

FILING DATE
December 10, 1999

GROUP
1644

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE
	AA						
	AB						
	AC						
	AD						
	AE						
	AF						
	AG						
	AH						
	AI						
	AJ						
	AK						

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION
	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>30</u>	Copy of co-pending U.S. application 10/149,138, inventors Fikes et al., filed December 11, 2002 (NOT PUBLISHED).
	AS		
	AT		

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.